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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,104	02/11/2002	Scott Arouh	DIA 0002DIV	9061

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,104	AROUH ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,14,15 and 27-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 14-15, 27-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 9/14/04 have been fully considered but they are not persuasive.

Applicant is advised that the body of their response lists the wrong application number and docket number in the header information.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 14-15 and 27-35 are pending and under consideration.

Information Disclosure Statement

Applicant is again reminded of their duty to disclose information relevant to the invention and is encouraged to file an information disclosure statement.

Claim Rejections - 35 USC § 112

Claims 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant points to section 1.1 and page 41, line 1 in support of claims 27-28. These sections do not describe a method of identifying from the genomic data of an individual organism a suitable therapy for at least one disease of the organism where at a time before the

training of the constructed neural network genomic data from the first group recited in the claim plus at least one member of the second group recited in the claim are obtained. (See also claims 33-34.)

Applicant points to page 28, line 10; pages 34-35; page 37, line 4; page 45; page 55; page 58; and pages 60-61 in support of claims 29-35. These sections are with respect to predicting clinical response, predicting drug response, predicting efficacy, predicting adverse drug reactions, optimizing drugs. These sections do not disclose a computerized method of identifying from the genomic data of an individual organism a suitable therapy (note that identifying a suitable therapy is not synonymous with predicting drug response, efficacy, adverse drug reactions, etc.) for at least one disease of the organism. These sections do not disclose a computerized method having the steps as set forth in claim 29 or a neural network residing on a computer and having the properties (e.g. suitable to map, trained by particular steps, functioning in a particular way) as set forth in claims 30-35.

Applicant is requested to point to support by page and line number in support of every limitation of these claims.

Claims 11, 14-15, and 27-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

This rejection is maintained for reasons of record.

Applicant argues that no *prima facie* case has been made. This is not agreed with. In keeping with *In re Marzocchi* the examiner has provided reasons to doubt the objective truth of the statements in the specification.

Many of applicant's arguments with respect to this rejection are not understood as they appear to address patentability with respect to the prior art. That is, the arguments appear to be directed to anticipation or obviousness. This is not germane to an enablement. (See pages 18-19 of response.)

Applicant is advised that none of the arguments set forth in the response with respect to data availability (see pages 20-23 of the response) can be addressed and are therefore not persuasive as the published references have not been provided. In addition, the Schork Declaration and Hypertension Response Prediction Final Report to NSF are not of record in this application. No documentation or evidence supporting the assertion regarding public availability of data has been provided.

Other publications referred to in the response cannot be addressed as they were not provided either.

Applicant has not pointed to any portion of the specification or provided any documentation supporting their contention that a family of genes or SNPs (including similarity of expression patterns and characteristic SNP patterns) had a well known and art understood definition at the time of the invention. As set forth in the prior Office action, the specification fails to identify any families and fails to define what they consider to meet the limitation of a family.

Applicant argues that diet type refers to the diet a person is on. Where is this discussed in the specification?

Applicant argues that home region is simply where someone lives. It is unclear whether this means their address or something more general. Where is this discussed in the specification?

Applicant appears to argue that these terms have a well known and art understood meaning that would have been known in the art at the time of the invention. This is not supported by the specification nor any evidence of record.

Applicant argues in the response that they have "enhanced the off-the-shelf neural network by using a genetic algorithm." (See page 26.) It is noted that only claims 14-15 and 31 have limitations to a genetic algorithm. Furthermore, it is unclear where in the specification that the enhancements to off the shelf neural network software are disclosed to provide guidance to one of ordinary skill in the art, particularly with respect to the reduced computational complexity required by claims 15 and 32. As set forth in MPEP 2106, applicant is reminded that along with a block diagram the disclosure must provide information that adequately describes each "element" in hardware or hardware and its associated software and how such elements are interrelated. See In re Scarbrough, 500 F.2d 560, 565, 182 USPQ 298, 301-02 (CCPA 1974) ("It is not enough that a person skilled in the art, by carrying on investigations along the line indicated in the instant application, and by a great amount of work eventually might find out how to make and use the instant invention. The statute requires the application itself to inform, not to direct others to find out for themselves (citation omitted)."); Knowlton, 481 F.2d at 1367, 178 USPQ at 493 (disclosure must constitute more than a "sketchy explanation of flow diagrams or a bare group of program listings together with a reference to a proprietary computer on which they

might be run"). See also In re Gunn, 537 F.2d 1123, 1127-28, 190 USPQ 402, 405 (CCPA 1976); In re Brandstadter, 484 F.2d 1395, 1406-07, 179 USPQ 286, 294 (CCPA 1973); and In re Ghiron, 442 F.2d 985, 991, 169 USPQ 723, 727-28 (CCPA 1971).

For the claims to be enabled, the specification, at the time the application was filed, must have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) discussed the factors to be considered in evaluating enablement. These factors include, but are not limited to, the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In the instant application the claims are broad. They are directed to a method of predicting a suitable therapy for at least one disease of an individual organism. The claims embrace all diseases, all therapies and drugs, all alleles and characteristic SNP patterns (known or unknown) related to any disease.

The nature of the invention is complex. The claimed method requires finding a computationally manageable solution, if any, using neural network computer technology to solve a complex genomic data problem. Claims 14-15, 31 and 32 further require genetic algorthim computer technology.

As reflected by the specification and art of record, the state of the art was such that those of ordinary skill in the art desired to predict a suitable therapy for disease from genomic data. That is, they had identified a problem whose solution was of interest to those of ordinary skill in the art. However, no one had successfully performed this method for any disease or drug.

The level of skill in the art would have been high, yet the prior Office actions have documented the art's difficulty or inability to link allele/SNP patterns to disease at the time of the invention. Applicant's method goes beyond this task to then link allele/SNP patterns to suitable therapy to treat the particular disease.

The level of predictability in the art would have been low. That is, given the lack of success in the art at the time of the invention, one would not have been able to predict that one of ordinary skill in the art would have been able to practice the method as claimed.

The instant application provides no specific direction to particular diseases, therapies or drugs, no specific alleles and/or characteristic SNP patterns for any disease. The instant application does not provide guidance as to what patients to study. The instant application does not provide guidance as to what data to collect, how to organize or partition this data, how to analyze it, what assumptions to make, such that one of ordinary skill in the art would have been in a position to construct, train and exercise a neural network as set forth in the claims to make the required predictions.

The instant application provides no working examples of the claimed method.

The method as claimed would require a large quantity of experimentation to make or use the invention based on the content of the disclosure.

The specification does not identify alleles or characteristic SNP patterns for any or all diseases. The claims require knowledge or the determination of alleles and characteristic SNP patterns to practice the method. The specification does not teach such alleles and characteristic SNP patterns for any disease. This is an invitation to experiment and constitutes undue experimentation. It would have required one of ordinary skill in the art to use inventive skill and judgment to develop the claimed method at the time of the invention.

The specification does not provide drug dosage results for a multiplicity of patients nor therapies. The specification does not reference any sources of such information. The specification does not provide any working examples of the method. The specification fails to provide guidance as to how to obtain the information required by the claimed method. As such, one would not be able to practice the claimed invention without undue experimentation.

Applicant is reminded that experimentation that requires ingenuity beyond that to be expected of one of ordinary skill in the art is considered undue. See Fields v. Conover, 170 USPQ 276. That is, one of ordinary skill in the art would have been required to adapt known genomic data and drug dosage data (select, compile, format, etc.) or generate the genomic data and drug dosage data required by the claims. Then one of ordinary skill in the art would have been required to decide how to use this data and develop the required neural network (with or without a genetic algorithm).

The claims are not enabled.

Claims 11, 14-15, 27-28, and 32-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 and dependent claims remain confusing for reasons of record. The preamble and body of claim 11 are inconsistent.

Claims 15 and 32 remain indefinite for reasons of record with respsect to grouping into families having "similar" expression patterns. The claims are not limited to householding or a binary definition of similarity.

Claim 27 recites "a first group consisting essentially of entire, gene families, specific alleles, ..." The recitation of "consisting essentially of" is confusing as it does not make clear what is included or excluded. That is, what particular property or characteristic is "essential" to members of the group? See also the second group recited in claim 27 as well as claims 28, 33, and 34. This rejection was not responded to.

Claim Rejections - 35 USC § 102

Claims 11, 14, 27-28, 30-31, and 33-35 remain rejected under 35 U.S.C. 102(e) as being anticipated by Roberts et al. (US 2003/0198970).

This rejection is maintained for reasons of record.

Applicant argues that this reference is not valid prior art. This is incorrect. The §102(e) date of this reference is the earliest U.S. filing date for which a benefit is properly sought under §§120, namely June 3, 1999. This is prior to applicant's effective filing date for these claims, namely July 6, 2000.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Marianne P. Allen
Primary Examiner
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mpa